Primary Analysis Results of the Phase 3 Archway Trial of the Port Delivery System With Ranibizumab for Patients With Neovascular AMD

Presented at Retina Society 2020

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Financial Disclosures

- CCA: Advisory Board: Allegro; Consultant: ArcticDx, Bausch + Lomb, Genentech, Inc., Katalyst, Volk; Stockholder: ArcticDx, Katalyst; Other: Allergan, Bausch + Lomb, Genentech, Inc.; Investigator: Adverum, Apellis, Genentech, Inc., GlaxoSmithKline, Hoffmann-La Roche, Kodiak, Merck, Mylan, Ophthotech, PanOptica, Regeneron, Stealth BioTherapeutics
- NS, DK, DK, SP, SG, GB: Employee: Genentech, Inc.

Study Disclosures

- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
- Funding was provided by Genentech, Inc., a member of the Roche Group, for the study and third-party writing assistance, which was provided by Betsy C. Taylor, PhD, CMPP, of Envision Pharma Group
Archway Met Primary Endpoint: PDS Q24W Equivalent to Monthly Ranibizumab

Equivalent Vision, Controlled Retinal Thickness
- PDS noninferior and equivalent for BCVA change at weeks 36/40
- PDS controlled retinal thickness as well as monthly ranibizumab through week 40

Treatment Durability, Reduced Treatment Burden
- 98% of PDS patients did not receive supplemental treatment before first refill-exchange
- ~5x fewer treatments through week 40 for PDS patients

Favorable Benefit-Risk Profile
- PDS surgery-device-drug combination was generally well tolerated
The Port Delivery System With Ranibizumab (PDS)

Continuous intravitreal delivery of a customized formulation of ranibizumab

Innovative, investigational drug delivery system

• Permanent, refillable intraocular implant
• Customized formulation of ranibizumab
• Implant surgically placed at the pars plana
• In-office refill-exchange procedures
Archway: Designed to Evaluate the Efficacy and Safety of the PDS for the Treatment of nAMD

Patients with nAMD responsive to any anti-VEGF treatment\(^a\)

\[ N = 415^b \]

Randomized 3:2

- **PDS with ranibizumab**
  - 100 mg/mL Q24W
  - \( n = 248 \)

- **Intravitreal ranibizumab**
  - 0.5 mg Q4W
  - \( n = 167 \)

Weeks 36 and 40: primary endpoint

- Week 96: final visit

**Primary objective**

Evaluate noninferiority and equivalence of PDS 100 mg/mL Q24W versus intravitreal ranibizumab 0.5 mg Q4W

**Primary endpoint**

Change in BCVA score from baseline averaged over weeks 36 and 40

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\( ^a \) nAMD in study eye diagnosed within 9 months of screening; \( \geq 3 \) intravitreal injections of any anti-VEGF agent within previous 6 months. \( ^b \) Efficacy- and safety-evaluable population. 418 total patients were enrolled, with 251 and 167 patients randomized to the PDS 100 mg/mL Q24W and intravitreal ranibizumab 0.5 mg Q4W arms, respectively; 3 patients in the PDS arm did not receive study treatment and were excluded from the efficacy- and safety-evaluable population. Archway, NCT03677934.

BCVA, best-corrected visual acuity; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; VEGF, vascular endothelial growth factor.
Eligible for supplemental intravitreal ranibizumab treatment with open-label intravitreal ranibizumab at weeks 16 and 20 (after implant insertion) and at weeks 40, 44, 64, 68, 88, and 92 if any of the 3 criteria were met.

**Criteria for Supplemental Intravitreal Ranibizumab: Disease Activity Due to nAMD**

<table>
<thead>
<tr>
<th>CST + BCVA</th>
<th>BCVA</th>
<th>CST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase of ≥ 100 µm on SD-OCT from lowest measurement and decrease of ≥ 10 letters from best recorded score</td>
<td>Decrease of ≥ 15 letters from best recorded score</td>
<td>Increase of ≥ 150 µm on SD-OCT from lowest measurement</td>
</tr>
</tbody>
</table>

* Eligible for supplemental intravitreal ranibizumab treatment with open-label intravitreal ranibizumab at weeks 16 and 20 (after implant insertion) and at weeks 40, 44, 64, 68, 88, and 92 if any of the 3 criteria were met. BCVA, best-corrected visual acuity; CST, central subfield thickness; D, day; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; RD, randomization; SD-OCT, spectral domain optical coherence tomography.
Baseline Demographics and Ocular Characteristics Were Well Balanced Across Treatment Arms

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PDS With Ranibizumab 100 mg/mL Q24W (n = 248)</th>
<th>Intravitreal Ranibizumab 0.5 mg Q4W (n = 167)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>Mean (SD) 75.2 (8.1) 51–96</td>
<td>Mean (SD) 74.8 (7.6) 54–89</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td>Male 41.5</td>
<td>Male 40.1</td>
</tr>
<tr>
<td>Baseline BCVA, ETDRS letter score</td>
<td>Mean (SD) 74.4 (10.5) 20/32</td>
<td>Mean (SD) 75.5 (10.3) 20/32</td>
</tr>
<tr>
<td>Baseline CPT, µm</td>
<td>Mean (SD) 176.9 (54.8)</td>
<td>Mean (SD) 177.2 (49.1)</td>
</tr>
<tr>
<td>Time since nAMD diagnosis, months</td>
<td>Mean (SD) 5.9 (9.5)</td>
<td>Mean (SD) 5.3 (2.0)</td>
</tr>
<tr>
<td>Number of prior anti-VEGF injections</td>
<td>Mean (SD) 5.0 (2.1)</td>
<td>Mean (SD) 5.0 (1.5)</td>
</tr>
</tbody>
</table>

98% study retention through week 40; no impact due to COVID-19

CPT measured from inner limiting membrane to the inner third of the retinal pigment epithelium.
BCVA, best-corrected visual acuity; CPT, center point thickness; ETDRS, Early Treatment Diabetic Retinopathy Study; nAMD, neovascular age-related macular degeneration; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; VEGF, vascular endothelial growth factor.
Adjusted means from a mixed-effect model for repeated measures (MMRM) analysis and vertical bars represent 95% CI. 95% CI is a rounding of 95.03% CI; the type 1 error was adjusted for interim safety monitoring. Adjusted means estimated using a MMRM with adjustment for change from baseline in BCVA as the response and included terms for treatment group, visit, treatment-by-visit interaction, and baseline BCVA (< 74 ETDRS letters vs ≥ 74 ETDRS letters).

**Primary Endpoint:** PDS Q24W Was Noninferior and Equivalent to Monthly Ranibizumab

<table>
<thead>
<tr>
<th>Time, Weeks</th>
<th>Adjusted Mean BCVA Change From Baseline, ETDRS Letters</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>-0.3 (1.7, 1.1)</td>
</tr>
<tr>
<td>8</td>
<td>-0.5 ETDRS letters</td>
</tr>
<tr>
<td>12</td>
<td>+0.5 ETDRS letters</td>
</tr>
<tr>
<td>16</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>20</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>24</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>28</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>32</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>36</td>
<td>+0.2 ETDRS letters</td>
</tr>
<tr>
<td>40</td>
<td>+0.2 ETDRS letters</td>
</tr>
</tbody>
</table>

*BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; VEGF, vascular endothelial growth factor.*
Primary Endpoint: PDS Q24W Was Noninferior and Equivalent to Monthly Ranibizumab

Adjusted means from a mixed-effect model for repeated measures (MMRM) analysis and vertical bars represent 95% CI. 95% CI is a rounding of 95.03% CI; the type 1 error was adjusted for interim safety monitoring. Adjusted means estimated using a MMRM with adjustment for change from baseline in BCVA as the response and included terms for treatment group, visit, treatment-by-visit interaction, and baseline BCVA (< 74 ETDRS letters vs ≥74 ETDRS letters).

BCVA, best-corrected visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; VEGF, vascular endothelial growth factor.

Adjusted mean BCVA change from baseline, ETDRS letters

- Expected transient postsurgical drop in vision
- Refill-exchange

Mean of 5.0 Previous Anti-VEGF Injections

Adjusted Mean BCVA Change From Baseline

Refill-exchange

+0.5 ETDRS letters

+0.2 ETDRS letters

PDS maintained vision over 40 weeks

<table>
<thead>
<tr>
<th>Baseline</th>
<th>Weeks 36/40</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETDRS Snellen</td>
<td>ETDRS Snellen</td>
</tr>
<tr>
<td>74.4</td>
<td>20/32</td>
</tr>
<tr>
<td>74.6</td>
<td>20/32</td>
</tr>
<tr>
<td>75.5</td>
<td>20/32</td>
</tr>
<tr>
<td>76.0</td>
<td>20/32</td>
</tr>
</tbody>
</table>

PDS with ranibizumab 100 mg/mL Q24W (n = 248)
Intravitreal ranibizumab 0.5 mg Q4W (n = 167)
PDS Patients With Baseline BCVA < 20/40 Experienced Similar Vision Gains as Monthly Ranibizumab at Week 40

**Baseline**

- **PDS With Ranibizumab 100 mg/mL Q24W**
  - 19.4% (n = 48) Worse than 20/40
  - 80.6% (n = 200) 20/40 or better
  - n = 248

- **Intravitreal Ranibizumab 0.5 mg Q4W**
  - 18.6% (n = 31) Worse than 20/40
  - 81.4% (n = 136) 20/40 or better
  - n = 167

**Week 40**

- **20/40 or Better Vision**
  - Baseline: 80.6% (200/248)
  - Week 40: 81.4% (136/167)

- **Gain of ≥ 5 Letters**
  - Baseline: 27.7% (13/47)
  - Week 40: 40.4% (19/47)

- **Maintained Vision ≥ 0 Letters**
  - Baseline: 74.5% (35/47)
  - Week 40: 61.3% (19/31)

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BCVA, best-corrected visual acuity; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks.
PDS Controlled Retinal Thickness Through Week 40 Similar to Monthly Ranibizumab

Adjusted Mean CPT Change From Baseline

Mean of 5.0 Previous Anti-VEGF Injections

Prespecified Secondary Endpoint, Week 36

Baseline | Week 36 | Change From BL
176.9 µm | 182.3 µm | +5.4 µm
177.4 µm | 180.0 µm | +2.6 µm

CPT defined as retinal thickness in the center of the fovea measured between the inner limiting membrane and the inner third of the retinal pigment epithelium layer. Adjusted means were estimated using a mixed-effect model for repeated measures with adjustment for change from baseline in CPT score as the response and included terms for treatment group, visit, treatment-by-visit interaction, and baseline best-corrected visual acuity (< 74 Early Treatment Diabetic Retinopathy Study [ETDRS] letters vs ≥ 74 ETDRS letters).

BL, baseline; CPT, center point thickness; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks; VEGF, vascular endothelial growth factor.
~98% of PDS-Treated Patients Did Not Receive Supplemental Treatment During First Refill-Exchange Interval

Percentage of PDS Patients Who Received Supplemental Treatment Before First Refill-Exchange at Week 24

PDS-treated patients: 248
PDS-treated patients who discontinued before first refill-exchange: 6
PDS-treated patients who received first refill-exchange: 242
  • Received supplemental treatment before first refill-exchange: 4
  • No supplemental treatment before first refill-exchange: 238

Number of supplemental treatments

~5x fewer treatments through week 40 for PDS patients
Serious Nonocular AEs Through Week 40

Systemic safety of PDS Q24W was generally comparable with monthly ranibizumab

<table>
<thead>
<tr>
<th>MedDRA Preferred Term, n (%)</th>
<th>PDS With Ranibizumab 100 mg/mL Q24W (n = 248)</th>
<th>Intravitreal Ranibizumab 0.5 mg Q4W (n = 167)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of patients with ≥ 1 AE</td>
<td>28 (11.3%)</td>
<td>16 (9.6%)</td>
</tr>
<tr>
<td>Overall total number of AEs</td>
<td>36</td>
<td>24</td>
</tr>
<tr>
<td>Pneumonia&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3 (1.2%)</td>
<td>0</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>2 (0.8%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Cerebrovascular accident</td>
<td>3 (1.2%)</td>
<td>1 (0.6%)</td>
</tr>
<tr>
<td>Syncope</td>
<td>0</td>
<td>2 (1.2%)</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>2 (0.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Chest pain</td>
<td>0</td>
<td>2 (1.2%)</td>
</tr>
<tr>
<td>Acute respiratory failure</td>
<td>2 (0.8%)</td>
<td>0</td>
</tr>
</tbody>
</table>

None of the serious nonocular AEs were suspected to be related to study treatment

<sup>a</sup> No cases were related to COVID-19.

Observed data, safety-evaluable population who received ≥ 1 dose of study drug according to the actual treatment. Events chosen with ≥ 2 events in either arm.

AE, adverse event; MedDRA, Medical Dictionary for Regulatory Activities; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks.
### Ocular Adverse Events of Special Interest<sup>a</sup>

PDS implant insertion and refill-exchange procedures were generally well tolerated.

<table>
<thead>
<tr>
<th>MedDRA Preferred Term, n (%)&lt;sup&gt;b&lt;/sup&gt;</th>
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<tr>
<td><strong>Time From Surgery</strong></td>
<td><strong>≤ 1 Month</strong></td>
<td><strong>&gt; 1 Month</strong></td>
</tr>
<tr>
<td>Conjunctival bleb/ conjunctival filtering bleb leak</td>
<td>11 (4.4%)</td>
<td>6 (2.4%)</td>
</tr>
<tr>
<td>Vitreous hemorrhage</td>
<td>12 (4.8%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Cataract&lt;sup&gt;d&lt;/sup&gt;</td>
<td>1 (0.4%)</td>
<td>9 (3.6%)</td>
</tr>
<tr>
<td>Conjunctival erosion</td>
<td>1 (0.4%)</td>
<td>5 (2.0%)</td>
</tr>
<tr>
<td>Conjunctival retraction</td>
<td>1 (0.4%)</td>
<td>4 (1.6%)</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>0</td>
<td>4 (1.6%)</td>
</tr>
<tr>
<td>Rhegmatogenous retinal detachment</td>
<td>1 (0.4%)</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>1 (0.4%)</td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>a</sup> Protocol-defined ocular adverse events of special interest potentially related to the PDS implant or implant procedure.  
<sup>b</sup> Frequency counts by Preferred Term. Multiple occurrences of the same adverse event in an individual are counted only once for each column.  
<sup>c</sup> All data through week 40.  
<sup>d</sup> Includes the following terms: cataract, cataract nuclear, cataract cortical, cataract subcapsular. Observed data, all treated patients who received ≥ 1 dose of study drug according to the actual treatment. Month 1 visit includes data up to 37 days (monthly study visit + 7 days).

- **Conjunctival bleb/ conjunctival filtering bleb leak**
  - 16 cases reported in total
  - 11 cases (4.4%) ≤ 1 Month
  - 6 cases (2.4%) > 1 Month

- **Vitreous hemorrhage**
  - 13 cases reported in total
  - 12 cases (4.8%) ≤ 1 Month
  - 1 case (0.4%) > 1 Month

- **Cataract**
  - 10 cases reported in total
  - 1 case (0.4%) ≤ 1 Month
  - 9 cases (3.6%) > 1 Month

- **Conjunctival erosion**
  - 6 cases reported in total
  - 1 case (0.4%) ≤ 1 Month
  - 5 cases (2.0%) > 1 Month

- **Conjunctival retraction**
  - 5 cases reported in total
  - 1 case (0.4%) ≤ 1 Month
  - 4 cases (1.6%) > 1 Month

- **Endophthalmitis**
  - 4 cases reported in total
  - 0 cases ≤ 1 Month
  - 4 cases (1.6%) > 1 Month

- **Rhegmatogenous retinal detachment**
  - 2 cases reported in total
  - 1 case (0.4%) ≤ 1 Month
  - 1 case (0.4%) > 1 Month

- **Hyphema**
  - 1 case reported in total
  - 1 case (0.4%) ≤ 1 Month

- **Cataract**
  - 10 cases reported in total
  - 9 cases (3.6%) ≤ 1 Month
  - 1 case (0.4%) > 1 Month

- **Conjunctival erosion**
  - 6 cases reported in total
  - 5 cases (2.0%) ≤ 1 Month
  - 1 case (0.4%) > 1 Month

- **Conjunctival retraction**
  - 5 cases reported in total
  - 4 cases (1.6%) ≤ 1 Month
  - 1 case (0.4%) > 1 Month

- **Endophthalmitis**
  - 4 cases reported in total
  - 4 cases (1.6%) ≤ 1 Month
  - 0 cases > 1 Month

- **Rhegmatogenous retinal detachment**
  - 2 cases reported in total
  - 2 cases (0.8%) ≤ 1 Month
  - 0 cases > 1 Month

- **Hyphema**
  - 0 cases reported

- **All cases**
  - 9 cases were addressed with flap revisions or coverage of implant flange with partial thickness cornea
  - 2 of 2 cases repaired with vitrectomy

- **Cases were predominantly subconjunctival thickening**
- **All were nonserious**

- **All cases of vitreous hemorrhage resolved spontaneously – no cases required vitrectomy**
- **1 of 248 PDS-treated patients had irreversible vision loss due to an adverse event (E. faecalis endophthalmitis)**
- **1 PDS patient experienced device dislocation into the eye during a refill-exchange procedure; following removal, the patient’s vision returned to baseline**

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<sup>a</sup> MedDRA, Medical Dictionary for Regulatory Activities; PDS, Port Delivery System with ranibizumab; Q4W, every 4 weeks; Q24W, every 24 weeks.
Conjunctival Bleb: Nonserious, Encapsulated Elevation of the Conjunctiva

MedDRA Preferred Term, n (%)\textsuperscript{b}

<table>
<thead>
<tr>
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\textsuperscript{a} All data through week 40.
MedDRA, Medical Dictionary for Regulatory Activities; PDS, Port Delivery System with ranibizumab; Q24W, every 24 weeks.

Conjunctival bleb

- 15 of 16 events
- Encapsulated elevation of the conjunctiva due to thickened Tenon’s capsule

Conjunctival filtering bleb leak

- 1 of 16 events
- Elevation of conjunctiva due to fluid
- Transient and resolved without treatment
PDS Patients With Retinal Detachment Continued on PDS Treatment With Good Vision Following Vitrectomy

Case 1
- Retinal detachment (day 16)
- Refill-exchange (day 24)
- Supplemental injection (day 40)
- Last Available BCVA
  - Recovered to 20/40

Case 2
- Retinal detachment (day 59) (day 108)
- Refill-exchange (day 24)
- Last Available BCVA
  - Returned to baseline (20/50)

BCVA, best-corrected visual acuity; D, day; PDS, Port Delivery System with ranibizumab.
Archway Met Primary Endpoint: PDS Q24W Equivalent to Monthly Ranibizumab

**Equivalent Vision, Controlled Retinal Thickness**
- PDS noninferior and equivalent for BCVA change at weeks 36/40
- PDS controlled retinal thickness as well as monthly ranibizumab through week 40

**Treatment Durability, Reduced Treatment Burden**
- 98% of PDS patients did not receive supplemental treatment before first refill-exchange
- ~5x fewer treatments through week 40 for PDS patients

**Favorable Benefit-Risk Profile**
- PDS surgery-device-drug combination was generally well tolerated

**PDS maintained vision while reducing treatment burden through continuous delivery of ranibizumab**

BCVA, best-corrected visual acuity; PDS, Port Delivery System with ranibizumab; Q24W, every 24 weeks.
Thank You to All Participating Archway Investigators, Study Sites, and Patients

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Brown, Jamin
Burgess, Stuart
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Campochiaro, Peter
Carlson, John
Chang, Margaret
Chaudhry, Nauman
Chen, Sanford
Clark, William
Crews, Kent
Dhoot, Dilscher
Dreyer, Richard
Eichenbaum, David
Engstrom, Robert
Falk, Naomi
Feiner, Leonard
Ferrone, Philip
Freeman, William
Goff, Mitchell
Goldberg, Roger
Gonzalez, Victor
Graff, Jordan
Gupta, Sunil
Haug, Sara
Heier, Jeffrey
Hershberger, Vrinda
Higgins, Patrick
Holkamp, Nancy
Hong, Bryan
Howard, James
Huddleston, Stephen
Jhaveri, Chirag
Johnson, Robert
Khanani, Arshad
Kitchens, John
Klancnik, James
Kwong, Henry
Lai, Michael
Lim, Jennifer
London, Nikolas
Marcus, Dennis
McCannel, Colin
Michels, Mark
Miller, Daniel
Mittra, Robert
Moore, Jeffrey
Nielsen, Jared
Ohr, Matthew
Phelps, Brian
Pieramici, Dante
Pollack, John
Rachitskaya, Aleksandra
Regillo, Carl
Schadlu, Ramin
Schneiderman, Todd
Sheth, Veeral
Sigler, Eric
Singer, Michael
Stoltz, Robert
Suan, Eric
Suner, Ivan
Tabassian, Ali
Thompson, John
Tosi, Joaquin
Wagner, Alan
Waheed, Nadia
Walker, Joseph
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Williams, Patrick
Wirthlin, Robert
Wolfle, Jeremy
Wong, Robert
Wykoff, Charles C.